STATEMENT OF WORK

OBJECTIVES

The Cancer Therapy Evaluation Program (CTEP) is responsible for the administration and coordination of most of the extramural clinical trials supported by the NCI's Division of Cancer Treatment and Diagnosis (DCTD). These programs include the activities of the NCI National Clinical Trials Network (NCTN), the Experimental Therapeutics Clinical Trials Network (ETCTN) and contract holders, the recipients of investigator-initiated grants and cooperative agreements relating to cancer treatment and the recipients of investigational agents. The Government is seeking a Contractor to provide direct organizational and information management support for these clinical trials programs and to provide support to the CTEP and DCTD Professional Staff in the acquisition, review and analysis of data to assist in the development, planning and conduct new clinical trials and information, which results from completed extramural research.

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, as set forth below.

The work is divided into five major Sections. They include but are not limited to:

I. Contract Transition (Phase-In)

II. Clinical Trials Information Support

III. Clinical Trials Project Management
   - A. Coordinate, Track and Support Accrual to CTEP-Sponsored Trials from Activation to Completion
   - B. Provide Project Management Support and Coordination to DCTD Correlative Science Studies (CSS)
   - C. Provide Project Management to NCI Precision Medicine Trials
   - D. Provide Project Management support to NCI's Early Drug Development Project Teams (PT)

IV. CCCT Scientific, Administrative and Logistical Meeting Support
   - A. Scientific Steering Committee Support
   - B. Task Force Support
   - C. Working Group (Ad-hoc) Support
   - D. Additional Administrative Support for Related Activities

V. Options
   - A. Increased Capacity
   - B. Phase-Out Transition

DESCRIPTION OF WORK

I. CONTRACT TRANSITION (Phase-In)

Upon approval of the Contracting Officer's Representative (COR). The Final phase-in transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities. Concerns anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued. Should a phase-in transition be required, the transition period shall be from May 1, 2016 to June 30, 2016. There will need to be concurrent work on implementing the transition plan and executing the Statement of Work to provide continuous support to all the activities as the majority of the work is time sensitive.

II. CLINICAL TRIAL INFORMATION SUPPORT

The Contractor shall provide support to the NCI professional staff in the acquisition of information and analysis of data to support developing new studies. These contract staff, referred to as Information Specialists, will also assist in analysis of data that result from clinical research and other program analyses needed. The data for possible analyses has had the personal identifying information (PII) removed by the NCI grantees prior to data submission to the NCI as part of their standard procedures. Many of these activities support NCI's mission of evaluating, prioritizing, coordinating, and analyzing planned and ongoing clinical trials and clinical research through mechanisms such as concept evaluations, scientific strategy and program meetings, clinical trial planning meetings, and special drug development meetings.

Examples of required support include, but are not limited to:

A. Provision of support for DCTD and CTEP scientific meetings and program analyses. This activity involves literature searches from currently available databases (e.g., CANCERLIT, MEDLINE, and PubMed), preparation of tables, data synthesis, and other material for presentation and/or distribution at meetings. Perform data base searches and analysis including, but not limited to, Index Medicus, National Library of Medicine (NLM) databases, Physician Data Query (PDQ), CLINPROT, The Cancer Genome Atlas (TCGA), and CTEP information systems.

B. Attendance by Information Specialists at meetings (e.g. clinical trial planning meetings, NCTN Chairs, Management & Operations Meetings, NCTN Lead Academic Participating Sites (LAPS) meetings, ETCTN and other scientific meetings) at the Contracting Officers' Technical Representative's (COR) direction and preparation of detailed minutes or summaries of these meetings.

NOTE FOR SUBPARTS A AND B: These meetings are often, but not always, held in the metropolitan Washington D.C. area, thus requiring some travel. Travel to work at scientific meetings shall be approved in advance by the COR. The meeting minutes and/or summaries shall be submitted to appropriate NCI staff within the time frame specified by the COR for comments and corrections and revised accordingly. This could be as little as within 24 hours but not more than 10 working days. The product may either be used for internal purposes only or may be used as a basis for NCI-generated scientific publications.

C. When necessary, the information specialists shall serve as advisors to NCI-sponsored investigators and their teams in the development of new Common Data Elements (CDE) as the scientific and/or trial need arises. NCI's CBIIT (Center for Biomedical Informatics and Information Technology), CCCT and CTEP are working in collaboration with the NCTN and ETCTN on a Network Medidata Rave Data Standards Committee (NRDS) to standardize the most widely analyzed CDEs utilized in NCI-sponsored clinical trials. This is part of a continued harmonization of data standards effort initially focused on NCI Networks (ETCTN and NCTN) currently using a common electronic Clinical Data Management System (eCDMS) (current system is Medidata Rave). Specifically, the Contractor shall:

1. Provide technical expertise to NRDS and investigators to assist in the creation of new data elements as necessary to keep up with changing science. This may include education and support to investigators to assist in the implementation of standardized Rave data elements, as

well as capturing investigator requests to extend existing CDE standards and handling those requests appropriately.

2. Participate in relevant NCI and Network data standards meetings, such as NRDS and its working groups, harmonization meetings, and appropriate CTEP and CBIIT meetings. Provide input to ensure that the NCI investigator community needs are well described and the implementation of Rave data standards include sufficient education of the NCTN members to facilitate adoption and ease of use of the new tools. Utilize training materials developed for the community adoption of data standards. Provide feedback and support to CBIIT as they develop and update training materials, such as a user instruction manual to guide the successful use of CDEs in a Network eCDMS.

D. Develop and maintain websites and/or databases for data sharing activities, including but not limited to the NCTN data sharing archive dataset that is under development now to become a publically available database in late 2015. Also, develop and maintain websites and/or databases scientific committees outside of the Scientific Steering Committee mechanism, including but not limited to the Gynecologic Cancer Intergroup Committee (GCIC), North American Breast Cancer Group (NABCG) and the Head and Neck International Group (HNIG). Provide administrative support to these activities, including but not limited to organizing meetings, conference calls, preparing call summaries, and tracking of action items and outcomes.

1. For the NCTN data sharing archive dataset, ongoing support will be needed to review data requests for completeness (projected to be a 3 to 4 months) according to the data sharing policies and procedures established by NCI. Coordination will be needed with NCI experts to review data request processes and provide input on any issues related to the processes or database that may need revision or enhancements over time.

2. For committees, tracking action items and outcomes may include clinical trial concepts that are reviewed outside the Scientific Steering Committee mechanism.

E. Maintain, enter, and retrieve information in various NCI and CTEP databases, which may include but are not limited to:

1. The CTEP Enterprise System (CTEP-ESYS) including IPAD and the NCTN Per Case Funding Management (PCMF) System
2. Cancer Trials Support Unit (CTSU) Regulatory Support Service (RSS) Reports
3. Secondary AML/MDS Database
4. Funding Information and Accrual Tracking System Database (FIATS)
5. CTEP Clinical Grants and Contract Branch (CGCB) Grants Publications Database
6. The IMPAC II Enterprise Program

F. Design data collection instruments (including databases) and develop data collection procedures for use in analysis of NCI-sponsored cancer clinical trials. Pertinent data might relate to any or all aspects of a subset (e.g. disease and stage specific) of cancer clinical trials, including study design, methodology, results, and quality of conduct (OMB Clearance is not required). At the direction of the COR, the databases developed may need to share data electronically with other CTEP and NCI systems; therefore, prior to development, review of the project needs shall include whether systems integration will be necessary.

G. Abstract, compile, collate, and analyze data utilizing a variety of resources available within and outside of NCI. Resources include, for example, published literature references, NCTN Group minutes and agendas, research progress reports, scientific meeting proceedings and white papers, and research protocols.

H. Summarize or otherwise process compiled data, and provide assistance to NCI in developing a comprehensive understanding of past, current and future research strategies and priorities.

I. Assist in the review of NCTN Group Concepts including analysis of ongoing activities and assistance in the form of literature searches and reviews of similar ongoing studies.

J. Assist in the review process for the NCTN Per Case Management Funding (PCMF) proposals submitted by the NCTN Groups during the protocol development phase and coordinate efforts with the CTEP PIO, DCTD, CTSU, DCP and others depending on the clinical trial.

K. Prepare drafts of reports for use by staff in carrying out NCI's mission of coordinating and maintaining an effective network of clinical trials organizations.

L. Assist in the writing and preparation of manuscripts, abstracts, posters or other publications for scientific publication including literature searches, preparation of initial drafts, copy editing, reference checking, and preparation of graphics.

M. Assist in the retrieval and analysis of information on clinical trials necessary for entry of data into the NIH Inclusion Management System (IMS).

N. Assist the NCI and CTEP staff in the conduct, retrieval, and analysis of information from:

1. Early-phase trial meetings
2. Special drug development sessions

O. Assist in abstracting planned accrual and planned accrual periods from original protocols for reporting on final trial outcome. To perform these tasks the Contractor will use data from NCI's supported research networks, such as NCTN and ETCTN, CTEP Enterprise databases and develop and/or maintain custom tracking approaches and tools.

P. Perform assessments of the quality and timeliness of their work and make quality improvements based on provided feedback to meet the needs of NCI. The Contractor shall work with the COR to make any adjustments to improve monitoring and performance of tasks.

Q. Participate, as needed, with NCI staff and other NCI designated Contractors to provide user feedback on software updates and needs to support NCI requested analyses and provide subject matter expertise involving the CTEP Enterprise System. At the direction of the COR, the Contractor's systems supporting NCI projects may need to share data electronically with other CTEP and NCI systems.

R. Maintain and update a Policy and Procedures Manual at least annually. This manual shall contain detailed operational procedures used in accomplishing the tasks described and should be made available on request to the COR.

S. The Project Manager and/or his or her representative shall be available for consultation and planning with the COR or other NCI staff on a short turnaround basis, such as within 48 hours, to discuss data management and procedures, protocol and/or forms revisions, planning meetings, problems encountered, procedures employed and other matters relating to the central management of the work. The Contractor shall implement a project management and task approval system to track tasks and subtasks and performance of the tasks.

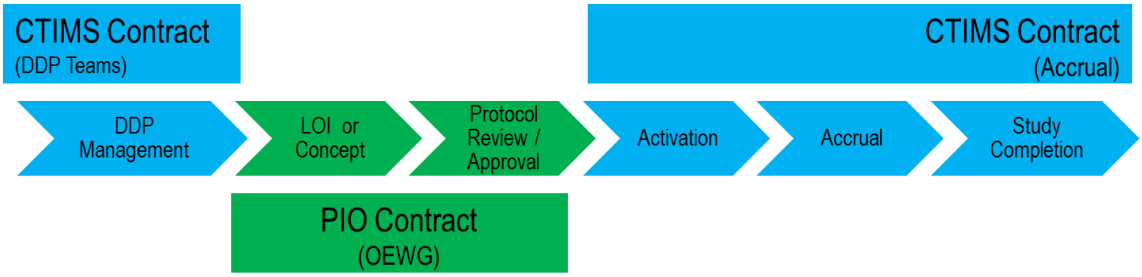
III. CLINICAL TRIALS PROJECT MANAGEMENT

The Contractor shall provide clinical trials project management support across four-sub-task areas. These contract staff, referred to as Clinical Trials Project Managers (PMs), shall work collaboratively with NCI Professional Staff to:

A. Coordinate, Track and Support Accrual to CTEP-Sponsored Trials from Activation to Completion
B. Provide Project Management Support and Coordination to DCTD Correlative Science Studies (CSS)
C. Provide Project Management to NCI Precision Medicine Trials
D. Provide Project Management support to NCI's Early Drug Development Project Teams (PT)

The Clinical Trials Project Managers (PMs) shall work collaboratively with NCI staff and the CTEP PIO Contractors to ensure timely trial activation and tracking of accrual to all studies in accordance with CTEP polices. CTEP's Protocol and Information Office (PIO) is the central coordinating and management unit for processing and organizing all protocol documents and will track OEWG trial activation timelines and implement the OEWG recommendations. Figure 1, below, illustrates major steps in the clinical trials development and completion process and distinguishes the oversight from the CTIMS Clinical Trials Project Managers (this contract) and the CTEP PIO Protocol Specialists.

Figure 1. Major Steps in the Clinical Trials Development and Completion Process and Relevant Oversight from CTIMS Clinical Trials Project Managers (blue) and CTEP PIO Protocol Specialists (green).



PMs will utilize NCI-developed guidelines for timely accrual and will work with CTEP and NCI staff to implement a comprehensive plan to enhance accrual to clinical trials, including NCTN and ETCTN clinical trials.

Additional Project Management support is needed for NCI's Precision Medicine clinical research projects to provide coordination to ensure their successful development, launch, completion and analyses, as well as to support the Early Drug Development Project (DDP) Teams.

Examples of required support for the four sub-tasks include, but are not limited to:

A. Coordinate, Track and Support Accrual to CTEP-Sponsored Trials from Activation to Completion

1. Interface with all trial support participants including NCI, NCI contractors and extramural professional and support staff to monitor trial progress.
2. Utilize existing NCI and site databases (including but not limited to CTEP-ESYS, IPAD, CTSU RSS, CIRB IRB Manager, and extramural investigator databases) to capture and track relevant accrual milestones and elements.
3. Develop additional local databases as necessary to capture pertinent information to meet specific project needs (e.g. additional tracking of accrual barriers, interventions that helped successfully overcome accrual challenges and interventions that did not work as well).
4. Collaborate with other NCI staff, contractors (e.g. CTSU, CIRB) and extramural study teams involved in trial activation and enrollment to minimize redundancy and address gaps in supporting trial accrual. It must be emphasized that PMs are not intended to replace or duplicate activities currently being performed by other NCI contractors or government staff, but rather it is intended to complement existing efforts and provide proactive coordination to ensure that protocol accrual timelines are met.

5. Arrange teleconferences and or/meetings including participants such as NCI staff, contractors, extramural study teams, NCTN members, and enrolling site staff to discuss and resolve critical accrual issues when necessary. Provide meeting summaries and/or notes. Follow-up with participants to ensure agreed-upon next steps are taken and document actions and responses.
6. Participate in appropriate meetings to maintain 'situational awareness' of trial accrual progress (e.g. NCTN Accrual Core Team, CTEP, Clinical Investigations Branch (CIB) and Investigational Drug Branch (IDB) meetings).
7. Develop prompts or triggers to alert appropriate personnel (e.g. extramural study teams, NCI staff) at major accrual timeline points and when key accrual statuses are noted.
8. As needed, escalate awareness of any issues that might delay trial accrual to the appropriate NCI and extramural site leadership.
9. By monitoring accrual information regularly, maintain up-to-date electronic reports documenting current status of each protocol accrual, which shall be a working/living document that gets updated in real-time and can be accessed on the shared drive. Reports shall be user-friendly and highlight and prioritize any potential or actual delays in accrual. The reports shall be able to be sortable by trial type (i.e. phase, lead site participant, disease, and CTEP coordinator). Reports shall reflect actual versus expected accrual. PMs will review these reports at least monthly with CTEP lead investigator/reviewer.
10. Develop accrual projections of studies and timelines upon request, working closely with NCI biostatisticians and NCI leadership to ensure highly accurate calculations used to develop projections.
11. Identify and implement any other tasks and/or processes that will facilitate and improve the protocol activation and completion process in collaboration with NCI staff and contractors in the CTEP PIO; including but not limited to the development of trial-specific materials (e.g., site activation guides, patient handouts, tailored emails to clinicians) and the conduct of audience research to identify accrual challenges at the site level.
12. The Contractor shall receive or access monthly accrual for NCTN and ETCTN trials, track accrual and accrual milestones according to the Early Stopping Guidelines for Slow Accruing Trials, and provide summary information to CIB and IDB investigators on trial slow accrual status and decisions or actions taken. Provide reports that reflect actual versus planned accrual rates and monitor and track patient demographics (race, ethnicity, gender, age) compared to the expected study patient population.
13. Identify potential impediments to achieve accrual goals (e.g. strict eligibility criteria, drug supply, scientific interest, results from other trials, industry contracts).
14. Maintain and organize minutes, drafts, and other pertinent documents in a local database suitable to meet project needs.
15. Coordinate with CTEP leadership, trial leadership and investigators regarding accrual corrective action plans (CAPS), including sending requests and coordinating and tracking CAPs received and outcomes.
16. Provide suggestions to address protocol specific and global impediments to patient accrual. Work with NCI staff, NCTN Groups and extramural investigators and their teams and others to collaborate on interventions to promote and enhance trial accrual.

B. Provide Project Management Support and Coordination to DCTD Correlative Science Studies (CSS)

1. Work with scientific leaders of DCTD and Center for Cancer Genomics (CCG) to coordinate the scientific review process for investigator proposals submitted to conduct CSS on specimens collected in NCI clinical trials.
2. Maintain up-to-date language for the CSS announcements and processes, including but not limited to the Genomic Characterization of Biospecimens collected from NCI studies and the NCTN Core Correlative Sciences Committee (NCTN-CCSC).
3. Coordinate with appropriate CTEP Operations and Informatics Branch (OIB), CTEP PIO and other NCI staff to integrate processes of the CSS with the standard operating procedures for review of trial specimen studies.
4. Provide regular updates to NCI scientific leaders on status of correlative science studies in the review process.
5. Work with CTEP and NCI leaders to leverage use of IT tools for tracking correlative science studies and analyzing for NCI program evaluation.

C. Provide Project Management to NCI Precision Medicine Trials

1. Provide meeting support for working groups in trial/study development. This includes but is not limited to setting up webinars, taking and/or transcribing minutes for review by working group chairs, sending out revised minutes to the working groups, and prompting and/or reminding study teams to address issues and action items in a timely fashion.
2. Interface with outside collaborators (e.g. pharmaceutical and device companies) to arrange meetings with trial/study investigators or working groups.
3. Attend working meetings; most meetings will be held in the Washington DC area but some travel may be required as approved in advance by the COR and CO.
4. Make slides/presentations/summaries for information to NCI, NIH and other officials, as well as other interested or involved parties.
5. As needed, escalate awareness of any issues that might delay trial progress in planning or accrual to the appropriate NCI and extramural site leadership.
6. Develop accrual projections of studies and timelines upon request, working closely with NCI biostatisticians and NCI leadership to ensure highly accurate calculations used to develop projections. Meet regularly with study leaders to ensure progress and identify barriers to goals.
7. Develop additional local databases as necessary to capture pertinent information to meet specific project needs (e.g. additional tracking of accrual barriers, interventions that helped successfully overcome accrual challenges and interventions that did not work as well).
8. Maintain and organize minutes, drafts, and other pertinent documents in a local database suitable to meet project needs.
9. Working with NCI investigators and others, prepare documents for CIRB and CTEP submission, and serve as point of contact for CIRB and CTEP reviewers.
10. Identify and implement any other tasks and or processes that will facilitate and improve the protocol activation and completion process in collaboration with NCI staff and contractors in the CTEP PIO.
11. Participate in appropriate meetings to maintain 'situational awareness' of trial accrual progress (e.g. Working Group, NCI leadership, OEWG, CIB and IDB meetings).
12. Provide suggestions to address protocol specific and global impediments to patient accrual or other deliverables. Work with NCI staff, NCTN Groups, other NCI groups and contractors and extramural investigators and their teams and others to collaborate on interventions to promote and enhance trial/study accrual.

D. Provide Project Management Support to NCI's Early Drug Development Project Teams (PT)

1. Work with NCI staff to execute Confidential Disclosure Agreements (CDAs) and vet Conflicts of Interest (COIs) of PT members
2. Work in coordination with the Investigational Drug Steering Committee (IDSC) to enable the Drug Development PTs to identify members and provide operational support for team meetings including but not limited to scheduling conference calls, providing call summaries, and collating presentations and materials.
3. Maintain timelines of ETCTN agents moving through the PT, Cooperative Research and Development Agreement (CRADA), IDSC and Senior Advisory Committee (SAC) review process.
4. Assist in the development and finalization of the PT presentation to the IDSC.
5. Assist in the development and management of the Share Point Drug Development and Drug Project Team site for the Investigational Drug Branch (IDB).

IV. CCCT SCIENTIFIC, ADMINISTRATIVE AND LOGISTICAL MEETING SUPPORT

Scientific, administrative, and logistical support for CCCT is broken into four task areas:

A. Scientific Steering Committee Support
B. Task Force Support
C. Working Group (Ad-hoc) Support
D. Additional Administrative Support for Related Activities

A. Scientific Steering Committee Support

The NCI currently supports sixteen (16) Scientific Steering Committees (SSCs) and one (1) Patient Advocate Steering Committee. It is anticipated that each steering committee will hold one (1) monthly meeting conference call or Webinar lasting approximately two (2) hours and in-person meetings as needed, usually one or two per year. Whenever possible the in-person meetings will be held in conjunction with a national scientific society meeting.

Scientific Steering Committee support will include support for Steering Committee meetings and Steering Committee concept evaluations. The Contractor shall work closely with CCCT Program Directors (PDs) to accomplish the following:

1. Provide Support for Steering Committee Meetings

a. Meeting Organization and Execution. The Contractor shall coordinate with CCCT PDs to oversee the administrative and logistic support of all steering committee related activities in conjunction with the Steering Committee co-chairs. Coordination requires:

   i. Obtaining a consensus of dates and times for conference calls, Webinars, in-person meetings
   ii. Confirming meeting (conference call, Webinar, in-person) dates and times with appropriate Steering Committee members, participants and NCI staff
   iii. Setting up conference calls through the NIH Conference Call System or NCI CBIIT WebEx conferencing. (NIH Teleconferencing: nihteleconf@mail.nih.gov; 301-496-4517, or https://cbiit.webex)
   iv. Forwarding meeting information to the Steering Committee members and other participants as directed by CCCT PDs
   v. Developing, modifying, and managing monthly conference call schedules and agendas as directed by CCCT PDs
   vi. Working with the CCCT PD to provide an annual clinical trial landscape. This may include a listing of NCI sponsored phase 1, 2 and 3 clinical trials, industry and international clinical trials. To this end the Contractor shall abstract, compile, collate, and analyze data utilizing a variety of resources available within and outside of the NCI. Resources include but are not limited to; clinicaltrials.gov, cancer.gov, NCI databases, published literature, and approved SSC concepts

b. Pre-Meeting Activities. In advance of Steering Committee meetings, the Contractor shall:
   i. Collaborate with Steering Committee Co-Chairs, the NCI Medical Officer (MO) and CCCT PD to develop the agenda and materials for each meeting and modify agenda and materials, as necessary
   ii. Develop a confidential annotated agenda for Steering Committee Co-Chairs and NCI staff as needed
   iii. Coordinate with CCCT PD to distribute the meeting agenda and materials to: 1) Steering Committee members, 2) NCI staff, 3) NCTN Group Chairs and 4) Other participants as directed by CCCT PD
   iv. Coordinate with CCCT PD to post meeting materials to the appropriate website

c. Meeting Activities. During the Steering Committee meeting the Contractor shall:

   i. Take role and determine quorum status if needed
   ii. Take notes to support post-meeting activities
   iii. Assist the CCCT PD in all meeting related activities

d. Post-Meeting Activities. Following the Steering Committee meetings, the Contractor shall:

i. Produce a summary of the meeting within three (3) business days of the meeting for conference calls and Webinars, ten (10) business days for in-person meetings. The meeting summary must be technically sound and reflect the scientific nature of the discussion
ii. Distribute draft meeting summary to CCCT PD for review
iii. Distribute preliminary meeting summary to the Steering Committee Co-chairs for their review prior to sending to the Steering Committee members
iv. Coordinate with CCCT PD to post any additional meeting-related materials to the appropriate website

2. Provide Support for Steering Committee Concept Evaluations

a. Concept Evaluation Organization and Execution. The Contractor shall coordinate with CCCT PDs to manage the concept evaluation process in conjunction with the CTEP/DCP, their respective Protocol and Information Offices (PIO) and Medical Officer (MOs), and Steering Committee Co-Chairs. Coordination requires:
i. After receipt of new and/or revised concepts inform SSC Co-chairs and members of the date/time of the evaluation and poll for a quorum
ii. After discussion with SSC Co-Chairs and CCCT PD and NCI MO, contact potential reviewers by email or telephone to request their participation in the concept evaluation
iii. Keep a running record (spreadsheet) of SSC members and the date and concepts evaluated
iv. Distribute concept(s) to reviewers and other participants as specified by CCCT PD
v. Electronically distribute the relevant call-in/WebEx information along with the date and time of the evaluation to all Steering Committee members
vi. Notify Study Investigator(s) of the date and time for evaluation of their concept
vii. One week prior to the scheduled call, send a reminder to evaluators with a due date for their evaluations
viii. Collect and collate evaluations and anonymize reviewers' identities in written documents
ix. Verify conference call/WebEx connection on the scheduled meeting day and call in 15 minutes prior to the scheduled call time
x. Take roll and assure that an appropriate quorum of members is present for voting
xi. Email ballot to voting members
xii. Receive and tally votes
xiii. Send voting results to CCCT PD within 24 hours after conclusion of meeting

b. Confidentiality and Conflicts of Interest. The Contractor shall manage all Confidentiality and Conflict of Interest (COI) activities. These include:
i. Distribute Confidential Disclosure Agreements (CDA) and COI forms to SC members and ad hoc reviewers. Collect and document updated COI forms annually
ii. Confirm that each reviewer has a COI agreement on file and screen for potential financial conflicts
iii. Assure that conflicted individuals, including the PI, research team and NCTN Group Leadership are not present for the deliberation of the concept

c. Pre-Meeting Materials. In advance of Concept Evaluations, the Contractor shall:
i. Prepare a draft agenda for the evaluation and obtain input and approval from CCCT PD
ii. Distribute the approved agenda to Co-Chairs for approval
iii. Prepare an annotated agenda for Steering Committee Co-Chairs and obtain input from CCCT PD if needed
iv. Distribute annotated agenda to Co-Chairs Send the agenda and minutes from the previous meeting to all Steering Committee members (minutes should not contain confidential information and should be available to everyone)
v. Obtain a written evaluation from all evaluators using the appropriate concept evaluation templates at least five (5) days prior to the evaluation meeting
vi. Collate all available reviewers' comments, de-identify and distribute all available comments and agenda two (2) days prior to the scheduled meeting
vii. Track late reviewers' comments and distribute de-identified comments as they are received

d. Post-Meeting Management. Following Concept Evaluations, the Contractor shall:
   i. Tally votes and notify CCCT PD of the results within 24 hours of the meeting
   ii. Following approval of CCCT, provide the appropriate NCI staff and Steering Committee Co-chairs with voting outcome and comments within twenty-four (24) hours of the meeting
   iii. Notify conference call participants of the outcome using standard language provided by CCCT and remind them of confidentiality

   iv. Within two weeks, obtain Draft Consensus Evaluation document from DCP/CTEP MO
   v. Distribute the Draft Consensus Evaluation document to the non-recused SSC membership and CCCT PD for review. The non-recused SSC membership and CCCT PD have three (3) business days to submit comments
   vi. Send all submitted comments to the NCI MO
   vii. Distribute the Final Consensus Evaluation document to the SC membership and CCCT.
   viii. Set up a post-evaluation conference call approximately two weeks after the concept evaluation for concepts receiving a vote of "pending with revisions". The participants of the call include the SC Co-Chairs, Concept PI and corresponding NCTN Group Chair or designee, NCI CIB/DCP MO, CCCT PD and other individuals as deemed necessary by CCCT PD
      a) Produce a summary of the meeting within three (3) business days of the meeting. The meeting summary must be technically sound and reflect the scientific nature of the discussion
      b) Distribute draft meeting summary to designated NCI staff for review
      c) Distribute preliminary meeting summary to meeting participants
   ix. Coordinate with CCCT PD to post any additional meeting-related materials to the appropriate website

B. Task Force Meetings

Note: Some Scientific Steering Committees (SSC) do not have any Task Forces (TFs), while others have as many as six (6); the average is approximately three (3) TFs per SSC. It is anticipated that each task force will hold one (1) meeting per month by conference call/WebEx lasting approximately one (1) hour.

1. Provide Support for Task Force Meetings

a. Meeting Organization and Execution. The Contractor shall coordinate with CCCT PD to oversee the establishment of standing conference calls/Webinars in conjunction with the TF Leadership. The coordination of these requires:
   i. Obtaining a consensus of dates and times for conference calls/Webinars
   ii. Confirming meeting dates and times with appropriate TF members and NCI staff
   iii. Setting up conference calls or NCI CBIIT WebEx conferencing through the NIH Conference Call System. (NIH Teleconferencing: nihteleconf@mail.nih.gov; 301-496-4517, or https://cbiit.webex.)
   iv. Forwarding dial-in information to the TF members and other participants as directed by CCCT PD
   v. Developing, modifying, and managing monthly meeting schedules and agendas as directed by CCCT PD

b. Pre-Meeting Materials. In advance of TF meetings, the Contractor shall:
   i. Collaborate with TF leadership and PD staff to develop the meeting agenda and meeting materials for each meeting and modify agenda and materials, as necessary
   ii. Distribute meeting materials and/or post to TF website
   iii. Set up the web-based tool(s) in use (if any) for TF meetings

c. Post-Meeting Materials. Following the TF meetings, the Contractor shall:
   i. Produce a summary of the meeting within three (3) business days of the meeting. The meeting summary must be technically sound and reflect the scientific nature of the discussion
   ii. Distribute draft meeting summary to designated CCCT PD for review
   iii. Distribute preliminary meeting summary to the TF leadership for their review prior to sending to the TF members
   iv. Distribute the meeting minutes and other materials to TF membership

v. Post final meeting minutes and approved materials to the Task Force website if applicable

C. Working Group (Ad-Hoc) Meetings

The Contractor shall work closely with CCCT Program Directors (PDs) to provide Support for Working Group (Ad-hoc) Meetings. Note: Working Groups are considered ad-hoc and are organized by the SC and Task Force leadership to do special tasks as needed.

1. Provide Support for Working Group (Ad-Hoc) Meetings

a. Meeting Organization and Execution. The Contractor shall coordinate with CCCT PD to oversee the establishment conference calls/webinar. Coordination requires:

i. Obtaining a consensus of dates and times for meetings
ii. Confirming meeting dates and times with appropriate members and NCI staff
iii. Setting up conference calls through the NIH Conference Call System or NCI CBIIT WebEx conferencing. (NIH Teleconferencing: nihteleconf@mail.nih.gov; 301-496-4517, or https://cbiit.webex)
iv. Forwarding dial-in information to the Working Group members and other participants as directed by CCCT PD
v. Develop, modify, and manage conference calls/Webinars and agendas as directed by CCCT PD

b. Pre-Meeting Materials. In advance of Working Group meetings, the Contractor shall:
i. Collaborate with Working Group leadership, and CCCT staff to develop the meeting agenda and meeting materials for each meeting and modify agenda and materials, as necessary
ii. Distribute meeting materials

c. Post-Meeting Materials. Following the Working Group meetings, the Contractor shall:
i. Produce a summary of the meeting within three (3) business days of the meeting. The meeting summary must be technically sound and reflect the scientific nature of the discussion
ii. Distribute draft meeting summary to designated CCCT PD for review prior to sending to the Working Group members

D. Additional Administrative Support for All Steering Committee/Task Force Related Activities

Additional support provided by the Contractor will include but not be limited to:

1. Communication

a. With NCI: The Contractor shall have weekly status call with CCCT PDs as requested. The purpose of the call is to discuss the details of the upcoming meetings/conference calls, agendas, meeting materials, distribution lists and any other information that is relevant to the functioning of the Steering Committee/Task Force activities.

b. With Steering Committee Co-chairs: The Contractor will coordinate with CCCT PD any conference calls that take place in-between standing monthly meetings, such as calls with the co-chairs and/or extra SC calls to facilitate work flow. All procedures outlined in Section III of the Statement of Work will be followed.

2. Steering Committee Co-chairs Conference Calls

The SC Chairs will have a minimum of three conference calls per year: Spring, Summer and Fall.

a. Meeting Organization and Execution. The Contractor shall coordinate with CCCT PD to oversee the establishment conference calls. Coordination requires:
i. Obtaining a consensus of dates and times for conference calls, working first with critical NCI leadership and the Chair of the SC Chairs
ii. Confirming conference call dates and times with all SC Chairs and NCI staff
iii. Setting up conference calls/Webinars through the NIH Conference Call System or NCI CBIIT WebEx conferencing. (NIH Teleconferencing: nihteleconf@mail.nih.gov; 301-496-4517, or https://cbiit.webex)

iv. Forwarding meeting information to all participants as directed by CCCT PD
v. Developing, modifying, and managing meeting materials as directed by CCCT PD

b. Pre-Meeting Materials. In advance of SC meetings, the Contractor shall:
i. Collaborate with CCCT PD and Chair of SC Co-Chairs staff to develop the meeting agenda and meeting materials for each meeting and modify agenda and materials, as necessary
ii. Distribute meeting materials

c. Post-Meeting Materials. Following the Task Force meetings, the Contractor shall:
i. Produce a summary of the meeting within five (5) business days of the meeting. The meeting summary must be technically sound and reflect the scientific nature of the discussion
ii. Distribute draft meeting summary to designated CCCT PD for review prior to sending to the Chair of the SC Co-Chairs

3. Membership

The Contractor shall coordinate with CCCT PDs to oversee the nomination and election of SC and TF members.

a. The Contractor keeps track of members terms of service
b. Six (6) months prior to the end of a member term the notifies CCCT PD and starts the nomination process
c. A nomination slate is formatted under the direction of the CCCT PD
d. The slate is sent by email along with corresponding Biosketches of the nominees
e. The Contractor tabulates votes and top candidates are contacted to ensure they understand the scope of responsibility and are able to commit the necessary time and gauge their level of interest
f. Notification letters are sent to the selected individuals by the Contractor under the direction of CCCT PD
g. The Contractor tracts members' attendance and provides quarterly reports to CCCT upon request

4. Concept Tracking

The Contractor shall keep track of concepts discussed in the TFs and evaluated in SCs using some agreed upon database or spreadsheet. Fields to track will be determined by CCCT PD.

V. OPTIONS

A. Increased Capacity

NCI includes increased capacity options to supplement the base contract to allow for additional support to cover an expansion of work in the major task areas mentioned at the beginning of the SOW that include: Clinical Trial Information Support, Project Management, and Scientific and Logistical Meeting Support. NCI is actively engaged in a Precision Medicine Initiative along with implementing recommendations from a national report for NCI to improve the national clinical trials system that may periodically require increased support.

B. Phase-Out transition

1. The Contractor shall prepare and submit a draft Phase-Out Transition Plan to the COR and the Contracting Officer 90 calendar days prior to the completion date of the contract. The plan shall describe the Contractor's strategy for transferring work from this contract to a successor contract, in the event a final transition would be required. The phase-out plan must include plans for transfer of policies and procedures; transfer of relevant files, records, materials, and data; transition of all activities, and transition of all applications, as appropriate. The Draft Phase-Out Transition Plan must include provision by the Contractor of accurate and complete data files and pertinent documentation. The draft Phase-Out Transition Plan will be revised, if necessary, and the Draft Phase-Out Transition Plan will become the Final Phase-Out Transition Plan upon approval of the COR.

2. In the event this project is re-competed during the life of this contract and the successor award is not made to the incumbent Contractor, a phase-out transition option period shall be utilized. This transition period shall encompass sixty days. The approved Final Phase-Out Transition Plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities by the contract completion date. Upon review and approval by the Contracting Officer and COR of the Contractor's FINAL Phase-Out Transition Plan, the Contractor shall provide the successor Contractor with detailed briefings regarding the policies and procedures for managing all aspects of the project. The successor Contractor shall also work in an apprentice capacity with this Contractor to insure that work operations are fully understood.

ADDITIONAL DELIVERABLES

In addition to the many deliverables that are part of the daily work listed within the major sections, the Contractor shall also provide:

1. Monthly Report - Within ten (10) calendar days of the first of each month, a brief monthly status report shall be provided. These reports shall include a description of work accomplishments during the period, including a list of all activities, status of each task, problems encountered, action taken, planned activities for the upcoming period, deadlines and any problems anticipated during the upcoming period.

Inspection of Deliverables. NCI staff working with the Contractor staff will provide timely review and inspection of deliverables. NCI will direct the Contractor when they need to provide draft versions of deliverables for scientific review and input. For example, Contractor staff preparing minutes from scientific meetings would send draft minutes to NCI, they would provide their review and edits, and the contract staff would finalize deliverable based on NCI input.

ACRONYMS AND REFERENCES

ACRONYMS

ALCHEMIST	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials (precision medicine study)
AML/MDS	Acute Myeloid Leukemia/Myelodysplastic Syndrome
CBIIT	Center for Biomedical Informatics and Information Technology
CCCT	Coordinating Center for Clinical Trials
CCG	Center for Cancer Genomics
CCR	Center for Cancer Research
CDA	Confidential Disclosure Agreements
CDE	Common Data Elements
CDMS	Clinical Data Management System
CDP	Cancer Diagnosis Program (within DCTD)
CGCB	Clinical Grants and Contract Branch
CIB	Clinical Investigations Branch (within CTEP)
CII	Cancer Informatics Infrastructure
CIP	Cancer Imaging Program (within DCTD)
CIRB	Central IRB
COI	Conflict of Interest
COR	Contracting Officers' Technical Representative
CRADA	Cooperative Research and Development Agreement
CRF	Case Report Form
CSS	Correlative Science Studies
CTAC	Clinical Trials and Translational Research Advisory Committee
CTEP	Cancer Therapy Evaluation Program (within DCTD)
CTEP-ESYS	CTEP Enterprise System
CTIMS	Clinical Trials Information Management and Support (this contract)
CTPM	Clinical Trial Planning Meeting
CTRP	Clinical Trials Reporting Program
CTSU	Cancer Trials Support Unit
CTWG	Clinical Trials Working Group
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DDP	Drug Development Plan
eCRF	Electronic Case Report Form
ETCTN	Experimental Therapeutics Clinical Trials Network
FIATS	Funding Information and Accrual Tracking System
IDB	Investigatory Drug Branch (within CTEP)
IDSC	Investigational Drug Steering Committee
IMPAC II	Information for Management, Planning, Analysis, and Coordination II (NIH internal database on grant applications and awards)

IMS	Inclusion Management System
IOM	Institute of Medicine
IPAD	Integrated Platform for Agents and Diseases
IRB	Institutional Review Board
IT	Information Technology
LAPS	Lead Academic Participating Sites (within the NCTN)
LOI	Letter of Intent
MATCH	Molecular Analysis for Therapy Choice (precision medicine study)
MO	Medical Officer
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute
NCORP	NCI Community Oncology Research Program
NCTN	National Clinical Trials Network
NCTN-CCSC	NCTN Core Correlative Sciences Committee
NIH	National Institutes of Health
NLM	National Library of Medicine
OIB	Operations and Informatics Branch
OMB	Office of Management and Budget
OPEN	Oncology Patient Enrollment Network
PCFM	Per Case Funding Management
PD	Program Director
PDQ	Physician Data Query
PIO	Protocol and Information Office
PMs	Project Managers
PT	Project Team
RSS	Regulatory Support Service
SAC	Senior Advisory Committee
SC	Steering Committee
SIS	Scientific Information System
SOW	Statement of Work
SSC	Scientific Steering Committee
TCGA	The Cancer Genome Atlas
TF	Task Force

REFERENCE WEB SITES

Cancer Therapy Evaluation Program (CTEP): http://ctep.cancer.gov/

CTEP Data Policies: http://ctep.cancer.gov/protocolDevelopment/cde_data_policies.htm

CTEP Slow Accrual Guidelines: http://ctep.cancer.gov/protocolDevelopment/docs/slow_accrual.pdf

Coordinating Center for Clinical Trials (CCCT): http://ccct.cancer.gov/

Clinical Trials Working Group (CTWG): http://restructuringtrials.cancer.gov/

CDE Browser: https://cdebrowser.nci.nih.gov/CDEBrowser/
https://wiki.nci.nih.gov/display/caDSR/caDSR+CDE+Browser

Clinical Trials Reporting Program (CTRP): http://www.cancer.gov/about-nci/organization/ccct/ctrp

Central Institutional Review Board (CIRB): http://www.ncicirb.org

CTSU (Cancer Trials Support Unit): https://www.ctsu.org/public/

CTSU/ Regulatory Support Service (RSS): https://rss.ctsu.org

NCI Center for Biomedical Informatics and Information Technology (CBIIT): http://cbiit.nci.nih.gov/

NCI Central Institutional Review Board Initiative (CIRB): http://www.ncicirb.org

OEWG Initiatives: http://ctep.cancer.gov/protocolDevelopment/OEWG.htm

Precision Medicine Initiative:
http://www.cancer.gov/news-events/nci-update/2015/precision-medicine-initiative-2016

Precision Medicine NCI-Sponsored Trials:
http://dctd.cancer.gov/MajorInitiatives/NCI-sponsored_trials_in_precision_medicine.htm

Scientific Steering Committees: http://www.cancer.gov/about-nci/organization/ccct/steering-committees